

# A Comparative Study on efficacy of FIBROTOUCH T100 and FIBROSCAN 402 to Determine Liver Elastography

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## ABSTRACT

**Introduction:** Liver Elastography is a new tool to assess liver disease stage and quantification of liver fat. Liver Elastography (Fibro Touch T100) is a simple, painless, non-invasive, reproducible novel tool with instant results to assess liver fibrosis. Fibro Touch T 100 has unique features that include a Single Probe for all patients irrespective of BMI and cost-effectiveness. Current research aimed to study the performance of Fibrotouch T100 in day to day clinical practice. To differentiate with Fibroscan in the assessment of Liver stiffness. To report the outcome from north coastal Andhra Pradesh, India and to compare with other studies.

**Material and methods:** The performance of Fibrotouch T 100 is compared to Fibroscan 402 in the present study. Head to head comparison was done at a single point in time in February 2019. Liver Stiffness Measurement (LSM) was noted, and other relevant clinical information was recorded. The data has been compared with other studies.

**Results:** A total of 90 subjects from north coastal Andhra Pradesh, India, were assessed. Male to female ratio was 71:19, and Mean Age was 40 years (20-74). Aetiology: HBV (31), HCV (3), HBV+HCV (1), Alcohol (22), Fatty Liver (33). The rates of successful detection were 100% by Fibro Touch and 97 % by Fibroscan 402. When compared with others, the results correlated.

**Conclusion:** Fibro Touch and Fibroscan have good consistency in non-invasive evaluation of the degree of liver fibrosis. Fibrotouch has a higher rate of successful detection than Fibroscan in obese patients. Fibrotouch T 100 is not only efficient but cost-effective.

**Keywords:** Fibrotouch, Fibroscan, Liver Elastography, Liver Fibrosis.

Indian Subcontinent.

The other causes of liver diseases are alcohol and Hepatitis B & C infections. Such patients will progress to chronic liver disease with fibrosis and cirrhosis while not having any symptoms in the initial stages and most often have normal traditional liver sonography.

By the time patients develop the symptoms like jaundice, ascites, encephalopathy, and gastrointestinal bleeding, liver disease is advanced, and therefore the life span of the patient is considerably reduced. The presence of significant Liver fibrosis is a major determinant of liver damage and mortality.

Without effective treatment, the advanced cirrhosis of the liver seriously influences the quality of living of the patients and places an intolerable burden on family and society. At present, in line with previous studies, it has been thought that liver fibrosis in the early stages is reversible. Therefore, the liver fibrosis in patients with chronic liver diseases should be accurately evaluated at early stages so that it can be treated in time, thus we can stop the progress of disease and scale back the prevalence of liver ailments.<sup>2</sup>

For several years, liver biopsy remained a "gold standard" for the diagnosis of liver inflammation and fibrosis. However, with its invasiveness, potential risks, and a few complications, liver biopsy is restricted in clinical application due to the poor acceptability and repeatability.

In recent years, liver fibrosis could be indirectly and accurately diagnosed via numerous diagnostic modalities like serologic biomarkers (example. FIBROTEST and APRI) and medical imaging technologies (example: Liver Elastography, VCTE, or MRE).

Transient elastography is a new technology within the field of ultrasonic imaging. Liver stiffness measurement (LSM) is

## INTRODUCTION

Liver diseases are common in India. According to the Indian Council of Medical Research, nearly 32% of the Indian population has liver ailments. Most liver diseases are asymptomatic early in the course of the disease and result in liver fibrosis and cirrhosis at later stages that account for 2,00,000 deaths in India per annum. Liver cirrhosis is one of the top ten causes of deaths worldwide, which accounts for 1/5th of the worldwide deaths. The most common cause for chronic liver disease in the present era is NAFLD (Non-Alcoholic fatty liver disease), along with obesity occurring in people with improper diet and lack of exercise, most patients have a tendency to get visceral adiposity, along with hyperlipidemias, hyperglycemia, and hypertension as reported by Yaron Rotman et al.<sup>1</sup> Metabolic syndrome and obesity are estimated to be up to 30 to 40 percent in the

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predicated on the speed of spread of acoustic wave in tissues that measures the stiffness of tissues.<sup>3</sup> It utilizes specific probes that send controlled low-frequency shear waves; these waves transmit high-frequency signals through liver tissues, which can track the way of transmission of the shear wave within the liver and therefore, the value of liver stiffness (kPa) is calculated within no time in reference to an inherent liver histologic model, that provides a quantitative standard for diagnosis of liver fibrosis of chronic liver disease. The higher LSM value means that the faster transmission of the shear wave, and therefore the harder of determining liver tissue.

Transient elastography (TE) utilizes specific probes to send out the fixed low-frequency shear wave for transient and active excitation on to the liver tissues and high-frequency signals to track the propagation of the shear wave in the liver and calculate the propagation speed in order to analyze the value of liver stiffness. Meanwhile, a patented algorithm and a built-in fat attenuation model are used to drive the signal attenuation coefficient of the liver, which is based on the attenuation of the high-frequency signal propagating through the liver. Accordingly, the fatty degeneration occurring in the liver is determined effectively and quantitatively. Stasi et al<sup>4</sup> explained the importance of non-invasive elastography as the diagnostic discriminator.

Liver Elastography (Liver Fibroscan and Fibrotouch T100) are new tools that help assess liver disease stage and quantification of liver fat, thereby eliminating the requirement for liver biopsy; it's an integrated diagnostic system for measurement of the amount of liver fibrosis and fatty liver. Patrick Marcellin<sup>5</sup> et al concludes that liver stiffness measurement appears to be reliable for the detection of fibrosis or cirrhosis. It provides the evaluating solution for liver fibrosis and fatty degeneration of the liver. Fibroscan is commonly used in practice for more than 10 years and widely standardized and validated for all aetiologies of liver diseases. Castera et al<sup>6</sup> reports that transient elastography fibroscan has excellent patient acceptance. Use of Fibroscan involves three probes S(Small), M(Medium), XL (Large) for liver assessment for different subjects based on weight, frame, BMI (Body Mass Index), and the depth of subcutaneous fat around the belly.

Novel Fibro touch T100 is a comparative, easy, painless, non-invasive, consistent tool with instant results to assess liver fibrosis severity. Fibro touch T 100 has distinctive features that comprise Single probe for all patients regardless of BMI and being cost effective.

Study aimed to investigate the efficiency of FibroScan 420 (FS) and Fibrotouch T100 (Hisky Foundation) (FT) in liver stiffness measurement (LSM) and fat quantification through a comparative analysis. To study the performance of Fibrotouch T100 in day to day clinical practice and to compare with Fibroscan in the assessment of Liver stiffness from north coastal Andhra Pradesh, India.

## MATERIAL AND METHODS

A cross-sectional study was done in 90 patients after taking

informed consent. We took informed consent from the participants before the study. Head to head comparison was done at that single point of time (Feb 2019), with a male and female ratio of (M: F) 71:19, With a Mean Age of 40 years (20-74). Out of which Hepatitis B patients are (31), Hepatitis C is positive in 3 patients, both Hepatitis B and C in 1, Alcohol (22), Fatty Liver (33).

The devices Fibrotouch T 100 and Fibroscan 402 are kept in separate rooms; after taking a thorough history and informed consent, patients are subjected to these rooms. The performance of Fibrotouch T 100 and Fibroscan 402 were noted separately, and accuracy is compared. Liver Stiffness Measurement (LSM) values obtained were noted.

Using an ultrasound transducer probe, vibrations of mild amplitude and low frequency sound waves are transmitted through the liver tissue. This results in an elastic shear wave that propagates through the underlying liver tissue. The probe then utilizes pulse-echo ultrasound to follow the propagation of the shear wave velocity. The velocity of the wave is directly related to tissue stiffness, which correlates with fibrosis. This method allows for the evaluation of various parameters, including the velocity of vibration, velocity of wave propagation, and elastic modulus.

TE allows for the identification of disease seriousness due to altered mechanical properties of the fibrotic liver. TE is a very easy, simple, and safe technique that takes 5–10 minutes and can be done in a specialty clinic or outpatient setting.

The differences in success rate and detecting parameters between FS and FT will be analyzed, as well as the correlation between FS and FT values.

FT – T100 uses energy attenuation of a signal propagating through the liver, calculate the signal attenuation coefficient of liver tissue and determine the fatty degeneration, and also various parameters of liver quantitatively to realize the non-invasive, quantitative, quick, and repeatable determination of fatty degeneration of the liver and provide results of liver fibrosis (Fibrosis score, in kilopascal's kPa) and fatty degeneration(UAP) in one test.

## Inclusion Criteria

Consecutive patients are seen at a tertiary care hospital and a private liver & gastro center in north coastal Andhra Pradesh, India with liver ailments of various aetiologies were included in this cross sectional study.

## Exclusion Criteria

- Subjects who are unable or unwilling to sign an informed consent form.
- Subjects who have other serious chronic disorders or a history of malignancy.
- Subjects with ALT  $\geq$  5 ULN in the past 1 month.
- Subjects with decompensated cirrhosis (especially the people with ascites).
- Subjects who have wound on the right upper abdomen recently.
- Subjects who have various space-occupying tumors or cyst in the right liver.



Figure-1: Fibrotouch and fibroscan used in the study.

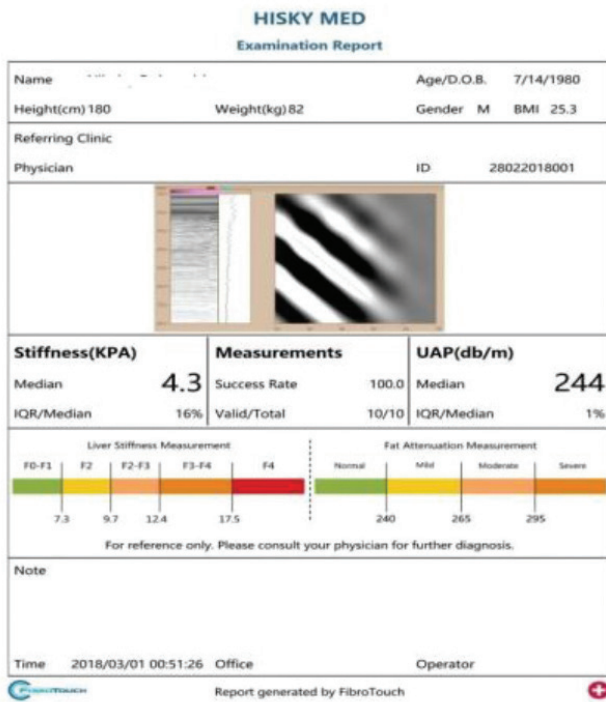
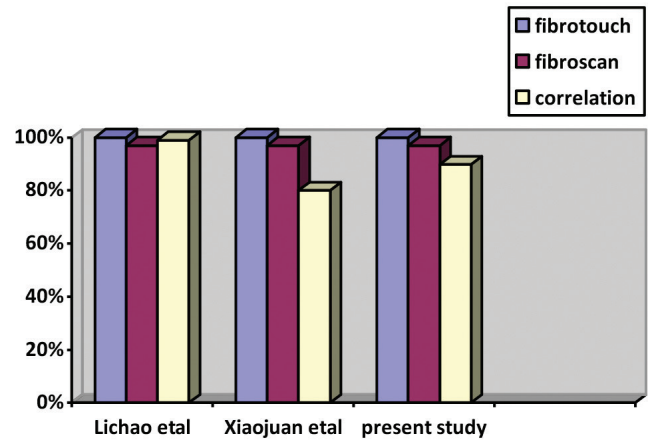


Figure-2: Sample reports from the study



Graph-2: Comparison of the present study with others

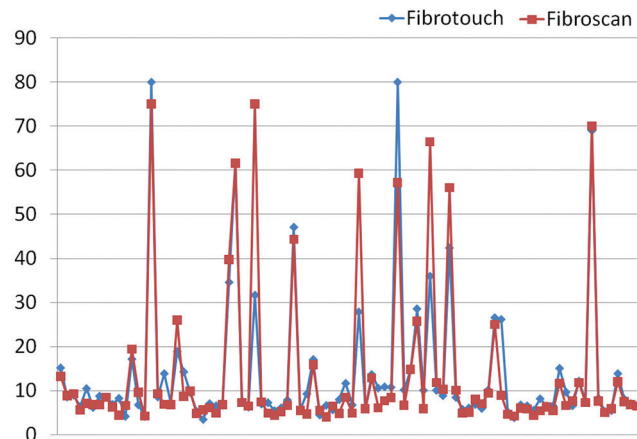
number of times of single detection than FS.

**CONCLUSIONS**

Fibro Touch and Fibroscan have good consistency in evaluation of the degree of liver fibrosis. Fibrotouch has a higher rate of successful detection than Fibroscan in obese patients. Fibrotouch T 100 is not only efficient but cost effective. The LSM and fat quantification of FS were significantly correlated with those of FT, both Based on the duration and number of times of single detection, success rate, and stability of fat quantification, FT seems to have a better detection efficiency than FS.

**DISCUSSION**

Liver Fibrosis is an important predictor of prognosis in patients with Chronic Liver Diseases. VCTE (Vibration Controlled Transient Elastography) is a validated, painless, simple, non-invasive tool to assess liver fibrosis. Fibroscan 420 (Ecosens) and Fibrotouch T 100 (Hisky Foundation) are similar devices that utilize the VCTE principle to determine liver fibrosis. Fibroscan 420 (Ecosens) has been widely validated in multiple studies in all forms of liver diseases, mainly chronic hepatitis C, Alcohol-related, and Non-Alcoholic Fatty liver disease, in the last decade. The main disadvantage with Fibroscan 420 is there is a need for three probes (small, medium, and XL probes) according to the patient weight, Body Mass Index, and depth of liver capsule from the skin surface to assess liver fibrosis. The three probes add up to the cost and make the procedure cumbersome.



Graph-1: Correlation of Fibro Touch & Fibroscan

**RESULTS**

The success rates were 100% for Fibro Touch and 97 % for Fibroscan 402, respectively, and the success rates were influenced by sex, age, body mass index, and biochemical markers of liver function. FT has a significantly shorter duration of single time detection and a significantly lower

Fibrotouch T100 (Hisky Foundation) is a novel device for fibrosis assessment that uses a single dynamic probe in all patients irrespective of Body mass Index making it cost-saving, and the availability of a footswitch makes the procedure with Fibrotouch T 100 more ergonomically efficient. The advantage of fibrotouch as a valuable diagnostic tool with good diagnostic accuracy has been proved by prior studies<sup>6</sup>

In the current study, we did head to head comparison of both Fibroscan 420 (Ecosens) and Fibrotouch T 100 (Hisky Foundation); we found an excellent correlation of Fpka (Fibrosis coefficient), suggesting similar efficacy in fibrosis assessment across all aetiologies. Similar observations were seen by Lichao et al<sup>7</sup> and Xiaojuan et al<sup>8</sup> in previous studies. As Fibrotouch T100 can assess steatosis with the UAP score, it is a distinct advantage over Fibroscan 420 (Ecosens) in patients with Non-Alcoholic Fatty Liver Disease (NAFLD). One more additional advantage of Fibrotouch T100 (Hisky Foundation) was its ability to assess fibrosis in morbidly obese subjects with Body Mass Index more than 35, as seen in the present study percentage unsuccessful with Fibroscan 420 (Ecosens).

The major limitation of the study was there was no liver histology assessment done as most patients were routine clinic patients, and subjecting them for liver biopsy, an invasive procedure with complications was not done. The minor limitation of the study was Standard Medium M probe was used in all patients with Fibroscan 420 (Ecosens), as there was a significant cost involved to procure the Small and bigger XL Probes.

To the best of the authors' knowledge, this was the first study in Indian patients with Fibrotouch T100 (Hisky Foundation) comparing with Fibroscan 420 (Ecosens), documenting similar efficacy for fibrosis assessment.

However, there is a need for multicentric studies with Fibrotouch T 100 and other comparative studies with Fibroscan 520 (Ecosens) before it can be widely used in clinical practice.

### Limitations of transient elastography

TE can't be utilized in individuals with ascites and is associated with higher failure rates or unreliable leads to obese patients using the standard M probe because the shear wave doesn't propagate through fluid, and fat conjointly attenuates ultrasound and elastic waves.

### CONCLUSION

FibroTouch and FibroScan 402 have reliable consistency in the evaluation of the degree of liver fibrosis. FibroTouch has a higher rate of successful detection than FibroScan 420 in diagnosing early stages of fatty liver, as it gives both kPa score as well as CAP score, whereas Fibroscan 420 gives only stiffness score.

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